CHAPTER 4

OFFICE OF THE GENE TECHNOLOGY REGULATOR

4.1 This chapter discusses the structure of the Office of the Gene Technology Regulator (OGTR) and its risk assessment processes compared with other stakeholder models. In addition, the chapter analyses whether the powers and investigative capability of the OGTR are adequate to ensure compliance with conditions imposed in licences. Finally, the chapter discusses the extent to which the proposed cost recovery and funding measures for the OGTR are appropriate and will allow for adequate resourcing of the Office.

Structure of the Office of the Gene Technology Regulator

4.2 The Bill proposes the establishment of the Gene Technology Regulator (GTR) as an independent statutory office holder with responsibility for implementing the legislation (clause 26). The Regulator is not subject to direction from anyone in relation to his or her performance, in particular whether or not to grant a GMO licence with or without conditions (clause 30).

4.3 The Regulator is appointed by the Governor-General, who is advised by the Commonwealth Minister for Health. In turn, the Minister for Health will be advised by the Ministerial Council. Before advising the Governor-General on the preferred appointee, the Health Minister must be satisfied that a majority of State and Territory Ministers support the appointment (clause 118). The Regulator will hold office for a fixed term of between three to five years (sub-clause 118(2)). The Regulator's appointment may also be extended for a further fixed term.[1]

4.4 The Regulator must disclose to the Minister all interests, pecuniary or otherwise, that could conflict with the performance of his or her functions (clause 120).

4.5 The functions of the Regulator (as set out in clause 27 of the Bill) include the following:

- determining applications for GMO licences;
- developing draft policy principles and policy guidelines to be issued by the Ministerial Council;
- developing codes of practice, technical and procedural guidelines in relation to GMOs;
- providing information and advice to other regulatory agencies and to the public;

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1 IOGTR, Additional Information dated 26 September 2000.

- undertaking or commissioning research in relation to risk assessment and biosafety of GMOs; and
- promoting the standardisation of risk assessment relating to GMOs and GM products by regulatory agencies.[2]

4.6 The Regulator may delegate any of his or her powers or functions to an employee of the Department of Health and Aged Care (DHAC), or an employee of another Commonwealth Department, authority or State agency whose functions relate to GMOs and GM products (clause 29). This enables the Regulator to delegate to a relevant agency such as the National Registration Authority (NRA) or the Australia New Zealand Food Authority (ANZFA).

4.7 The Bill also establishes the Gene Technology Account, over which the Regulator will have complete responsibility, and it allows for staff to be recruited by the Regulator.[3]

4.8 The Regulator has discretion in the performance of his or her functions, and has the ability to obtain scientific, ethical and other advice from the three advisory committees established by the Bill. The Regulator, is however, bound by policy principles issued by the Ministerial Council not to issue a licence if to do so would be inconsistent with a policy principle (clause 57).[4] Policy principles are discussed in Chapter 5. The Regulator must report to the Minister annually and also has the discretion to table a report in either House of Parliament about matters relating to his or her functions at any time (clause 137).[5]

Independence and accountability

4.9 Evidence to the Committee emphasised the necessity for the Regulator to be independent and also to be seen to be independent in its important regulatory role.[6] The Australian Food and Grocery Council (AFGC) stated that 'to be effective, the office must be independent…the operational framework must ensure that the office is independent of commercial, political and sectoral influence'.[7]

4.10 Some submissions argued that the Bill fails to establish adequate safeguards to ensure the independence of the Regulator. As noted above, the Regulator must disclose to the Minister all interests, pecuniary or otherwise, that could conflict with the performance of his or her functions (clause 120).

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2 Explanatory Memorandum, Gene Technology Bill 2000, p.55.

3 Submission No.77, p.53 (IOGTR).

4 Submission No.41, p.6 (Grains Research & Development Corporation).

5 Department of the Parliamentary Library Bills Digest No 11 2000-01, Gene Technology Bill 2000, dated 16 August 2000, p.11. See also Submission No.77, pp.53-7 (IOGTR).

6 Submission No.110, p.2 (South Australian Government); Submission No.70, p.1 (Professor Gibbs); *Committee Hansard*, 25.8.00, p.399 (AFGC).

7 *Committee Hansard*, 25.8.00, p.399 (AFGC).

4.11 The Australian Centre for Environmental Law (ACEL) argued that the provisions needed to be strengthened and that an individual with an interest (financial or otherwise) in a regulated entity should be precluded from holding the office of Regulator. Likewise, an individual who has worked in a regulated entity should be barred from holding the office until the expiration of an adequate amount of time, such as two year, to ensure propriety and the appearance of propriety in impartial decision making. The Centre argued that disclosure of interest 'is clearly not sufficient' in these areas.[8]

4.12 The Committee believes that given the importance of the Office of the Regulator and the necessity of ensuring community confidence in its independence and impartiality strict eligibility criteria to the appointee should apply.

Recommendations

The Committee RECOMMENDS that an individual with a financial or other interest in a regulated entity be precluded from holding the office of Regulator.

The Committee RECOMMENDS that an individual who has worked for a regulated entity be precluded from holding the office of Gene Technology Regulator until the expiration of a two-year period.

4.13 Submissions also noted that the proposed requirement that the Regulator be 100 per cent self-funded imposes a very significant restriction on his or her independence. Submissions noted that the proposed cost recovery arrangements can give rise to the perception that the Regulator is a 'captive' of industry. This in turn can reduce the public's trust in the Regulator's decisions.[9] The Committee is not persuaded as to the need for a system of full cost recovery. This issue is discussed later in this chapter.

4.14 Several submissions noted the importance of the establishment of a fixed term of tenure for the Regulator to ensure his or her independence under the Bill.[10] Professor Gibbs also argued that the term of tenure should not be renewable – 'the person in this position will have great responsibility and power'.[11] The Committee considers that the office should be renewable especially given that the proposed term of office is relatively short (between three to five years), and that similar officeholder positions are usually renewable.

4.15 The Committee notes that the Regulator will be required to report annually to the Parliament. The Committee believes that the transparency of the operations of the Regulator would be enhanced if the Regulator reported more frequently than annually.

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8 Submission No.34, p.6 (ACEL); *Committee Hansard*, 25.8.00, pp.358-9 (ACEL) See also Submission No.9, p.7 (HSCA).

9 Submission No.32, p.9 (Avcare Ltd); Submission No.71, p.9 (AFGC).

10 Submission No.85, p.13 (ACF GeneEthics Network); Submission No.70, p.1 (Professor Gibbs).

11 Submission No.70, p.1(Professor Gibbs).

The Committee notes that the recent House of Representatives report into gene technology recommended that the Regulator report at least quarterly for the first three years.[12]

4.16 The Committee believes that the Regulator should be required to report quarterly with regard to compliance with the legislation. The Australian Radiation Protection and Nuclear Safety Authority, which has similar regulatory functions to that proposed for the Regulator in the Gene Technology Bill, provides for quarterly reporting. Section 60 of the *Australian Radiation Protection and Nuclear Safety Act 1998* provides that the agency must include, *inter alia*, details of any breach of licence conditions by a licensee and a list of all facilities licensed during the quarter in its quarterly reports. The Committee considers that this type of information provides a useful model for the reporting requirements that should be provided by the Regulator under the Gene Technology Bill in its quarterly reports.

Recommendation

The Committee RECOMMENDS that the Bill be amended to include a requirement for quarterly reporting by the Regulator and that these reports include relevant information on the functions and operations of the Regulator including facilities licensed and breaches of licence conditions.

Establishment as a statutory authority

4.17 Some evidence suggested that the independence of the office would be increased if the Regulator were established as an independent statutory authority.[13] The Consumer Food Network of the Consumers' Federation of Australia (CFN) argued for the establishment of a statutory authority governed by an independent board and reporting to a Cabinet Minister, preferably the Minister for Health or the Minister for the Environment.[14]

4.18 The Interim Office of the Gene Technology Regulator (IOGTR) noted that initially some jurisdictions expressed a preference for the Regulator to be established as a statutory authority, however, following consideration of the issue, 'all jurisdictions agreed that a statutory office holder with budgetary control, control over staffing and control over decision making in respect of individual applications would deliver the essential outcomes'.[15] The South Australian Government while supporting this position, however, expressed the view that the independence of the Regulator would be further enhanced if constituted as a statutory corporation established jointly

12 *Work in Progress: Proceed with Caution*, Report by the House of Representatives Standing Committee on Primary Industries and Regional Services, June 2000, p.139.

13 Submission No.88, p.3 (NFF); Submission No.71, p.6 (AFGC).

14 Submission No.50, p.2 (Consumer Food Network). See also Submission No.6, Appendix 1 (Consumers' Association of SA).

15 Submission No.77, p.53 (IOGTR).

by the Commonwealth and States – 'further, we believe that such an authority may provide a more secure constitutional basis for the administration of the scheme'.[16]

4.19 The IOGTR noted that the proposed option of a statutory office holder will provide a high level of independence, transparency and accountability.[17] The IOGTR noted that the Bill provides that Regulator as a statutory office-holder with a high level of autonomy in administering the legislation, and in financial and staffing matters.[18] AFGC also noted that although not established as a statutory authority – the Council's preferred approach – the status afforded the Regulator 'being appointed by the Governor General and reporting directly to Parliament, should provide industry and consumers with considerable confidence in the independence and apolitical nature of the office and the system'.[19]

4.20 The Committee believes, however, that the need for all decisions made by the Regulator to be not only scientifically based but entirely independent is crucial to ensuring public confidence in the regulatory system. The fact that under the current proposal the final decision rests with one person is of concern in terms of the level of responsibility and pressure this one person will have and perceptions that one person may not be able to resist pressure from outside influences, industry or Government. This being the case the Committee recommends that the independence and impartiality of the office will be enhanced by the establishment of the Regulator as a statutory authority, where a board of three people will take ultimate responsibility for decision-making.

Recommendation

The Committee RECOMMENDS that the Regulator be established as a statutory authority consisting of a board of three people who will take ultimate responsibility for decision-making.

Interface with existing regulators – 'one-stop shop' model

4.21 Under the proposed Bill, the Regulator operates as a 'gap filler' regulating all dealings with live viable GMOs and also GM products not regulated by existing regulators. The Bill regulates all 'dealings', including research, manufacture, production, propagation, commercial release and import, with live viable GMOs that have been modified by techniques of gene technology. This recognises that at present most of the 'gaps' in legislative oversight exist in relation to dealings with live viable organisms. The legislation will also regulate GM products – non-live or non-viable products – where they are not regulated by an existing regulatory regime. This recognises that most GM products are regulated by existing regulatory regimes, for

16 Submission No.110, p.2 (South Australian Government).

17 Submission No.77, p.73 (IOGTR).

18 Submission No.77, p.53 (IOGTR).

19 Submission No.71, p.6 (AFGC).

example, GM medicines, foods and chemicals, but there may be some products that are not currently regulated, for example, stock feed.[20]

4.22 Evidence from consumer, environmental and primary producer groups argued that the Gene Technology Regulator should be a 'one stop shop' for the regulation of GMOs and GM products.[21] Under this approach, all GMOs and GM products would be regulated by a single agency or through a centralised process regardless of whether the GMOs or GM products were also therapeutic goods, foods, agricultural and veterinary chemicals or industrial chemicals.

Scope of the scheme

4.23 Some submissions argued that the proposed scheme should subject every activity, application and use of GMOs or products derived from GMOs to a unified regulatory control, administered by one independent regulator. ACEL argued that the activities regulated should include all applications and uses of GMOs; the development, breeding, propagation, production and manufacture of GMOs; deliberate releases into the environment; marketing of GMOs; contained use of GMOs; and import and export of GMOs.[22] Friends of the Earth (Fitzroy) also stated that the regulatory system should have the powers to consider all GMO and GM products.[23]

4.24 Other submissions argued that the establishment of a 'one-stop shop' would not necessarily mean that the Regulator would have to be a 'super-regulator'. The Consumer Food Network argued that much of the assessment work could be done by particular agencies such as ANZFA, NRA, the Therapeutic Goods Administration (TGA), the Australian Quarantine and Inspection Service (AQIS) and the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). The Network argued that the Regulator should, however, have ultimate responsibility for coordinating the assessments and licensing of GMOs and their products.[24]

4.25 Other submissions also discussed possible structures for a 'one-stop shop' arrangement. ACF GeneEthics Network argued that that the OGTR should be the lead agency in all GE-related matters. In the first instance, all applications would pass through a single entry point to the OGTR. In addition to doing its own assessments, the OGTR would commission its subcommittees and other authorities, such as Environment Australia, to assess particular applications from their perspectives – 'this

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20 Explanatory Memorandum, p.18.

21 *Committee Hansard*, 24.8.00, p.265 (NGAA); *Committee Hansard*, 24.8.00, p.287 (AWB Ltd); *Committee Hansard*, 24.8.00, p.306 (ACF); Submission No.6, p.3 (Consumers' Association of SA); Submission No.85, p.10 (ACF GeneEthics Network); Submission No.34, p.3 (ACEL); Submission No.54, p.22 (OFA); Submission No.88, Attachment 2 (NFF); Submission No.63, p.7 (AWB Ltd); Submission No.59, p.2 (MLA).

22 Submission No.34, pp.3-4 (ACEL).

23 Submission No.51, p.10 (Friends of the Earth (Fitzroy)).

24 Submission No.50, p.1 (Consumer Food Network).

would provide broad advice, and robust, credible assessments which would have a much better chance of winning public confidence'.[25]

Advantages of a 'one-stop shop' approach

4.26 Proponents of a 'one-stop shop' approach argued that this model would ensure comprehensive regulation of all activities and dealings involving GMOs or GM products and a streamlined assessment process requiring approval from only one regulator.[26] The ACF GeneEthics Network argued that:

> The GT Bill does not fundamentally reform the existing voluntary system of advice and unenforceable guidelines. It creates an irrational situation where many authorities assess applications for some dealings with, and products of GEOs, under a variety of laws and powers. Each application may go separately to several bodies, but in some cases may never need to be notified to, or be considered by, the OGTR.[27]

4.27 Meat and Livestock Australia Ltd (MLA) also argued that the 'relative complexity of the current and proposed regulatory systems add cost and uncertainty, which discourages investment in gene technology'.[28] In some cases, businesses will require approval from a number of regulators in order to market a GM product. For example, GM crops will be regulated as they are growing in the field by the Regulator and also by ANZFA if they are intended to enter the food chain.[29]

4.28 Evidence also suggested that a 'super-regulator' may provide more transparency and certainty for community members who have serious concerns regarding gene technology. Community concerns and input about the impacts of GMOs on human health and safety and the environment could have maximum effect as they would be focussed on a single regulatory system.[30]

The 'gap-filler' approach

4.29 As noted above, the Bill regulates all dealings with live viable organisms that have been modified by techniques of gene technology (regardless of whether these are also examined by other regulators). In relation to GM products, that are not live and viable, and:

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25 Submission No.85, p.10 (ACF GeneEthics Network). See also Submission No.35, p.7 (GE-Free Tasmania).

26 Submission No.34, p.3 (ACEL); Submission No.54, p.22 (OFA).

27 Submission No.85, p.10 (ACF GeneEthics Network).

28 Submission No.59, p.2 (MLA).

29 Explanatory Memorandum, pp.18-19.

30 Submission No.85, pp.9-11 (ACF GeneEthics Network); Submission No.6, pp.1-4 (Consumers' Association of SA). See also Explanatory Memorandum, p.20.

- are not regulated by any other regulatory agency – the Regulator will directly regulate those GM products (for example, stock feed); and
- are regulated by other regulatory agencies – the regulatory agency must seek, and take into account, the Gene Technology Regulator's advice and must notify the Regulator of the decision regarding the GM product so that the GTR can include the information on a comprehensive database of GMOs and GM products approved for use in Australia.[31]

4.30 The IOGTR stated that the Gene Technology (Consequential Amendments) Bill 2000 'creates a statutory requirement for each of the other regulators of GM products to seek advice from the Gene Technology Regulator in respect of any biosafety matters arising from a GM product'.[32]

4.31 The Consequential Amendments Bill amends the current Commonwealth regulatory schemes to require the relevant regulatory agency to request advice from the Regulator, and to consider that advice when making decisions in relation to products which are GM products or contain GM products. The regulatory agencies must also notify the Regulator of decisions made in relation to GM products, so that these decisions can be included on the Record of GMO and GM Product Dealings.

4.32 The Consequential Amendments Bill amends:

- the *Agricultural and Veterinary Chemicals (Administration) Act 1992* and the *Agricultural and Veterinary Chemicals (Code) Act 1994*;
- the *Australia New Zealand Food Authority Act 1991*;
- the *Industrial Chemicals (Notification and Assessment) Act 1989*; and
- the *Therapeutic Goods Act 1989*.[33]

4.33 These amendments give the formal legislative basis for the interaction between the existing regulators and the Gene Technology Regulator in terms of requesting and providing information, making decisions and establishing publicly available information systems. This approach requires amendments to the above-mentioned primary legislation and the implementation of formal channels of communication between the regulators and the Gene Technology Regulator.[34]

4.34 The Parliamentary Library stated that the regulatory agencies do not have to follow the Regulator's advice, although they must have regard to it. If a regulatory

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31 Submission No.77, p.71 (IOGTR).

32 *Committee Hansard*, 14.8.00, p.31 (IOGTR).

33 The Attorney-General's Department operates a database of Acts which is updated regularly. There are also legal updating services that update legislation and there are tables that accompany Acts indicating where amendments to the relevant Acts have been made.

34 Explanatory Memorandum, Gene Technology (Consequential Amendments) Bill 2000.

agency approves a licence or registration or other dealing with GM product, in contravention of the Regulator's advice, there is no provision requiring this fact to be made public. The Record of GMO and GM Product Dealings contains information relating to the person authorised, and any conditions specified in the licence or authority, but does not contain copies of documents such as the Regulator's written advice or any risk management plans.[35]

4.35 The impact of the proposed changes as it applies to agricultural and veterinary chemicals, food, industrial chemicals, therapeutic goods and the import of GMOs is discussed below.

Agricultural and Veterinary Chemicals

4.36 The Consequential Amendments Bill would require the National Registration Authority to consult the Regulator if an active constituent or a chemical product is or contains a GM product. The NRA must give written notice to the Regulator that an application has been made involving a GM product, and seek the advice of the Regulator, in relation to decisions concerning the:

- approval, variation or reconsideration of an approval of an active constituent;
- registration, variation or reconsideration of the registration of a chemical product;
- approval, variation or reconsideration of an approval of a chemical product's container label; or
- issue of a permit to allow a person to do something with an active constituent or a chemical product that would otherwise be prohibited.

The Regulator must provide the advice requested, in writing, within a specified time period, and the NRA must take that advice into account in determining the application. The NRA is not obliged to follow any advice given by the Regulator, but must inform the Regulator of the NRA's final decision.[36]

Food

4.37 The Consequential Amendments Bill would amend the *Australia New Zealand Food Authority Act 1991*. The effect of this change would require that ANZFA, after accepting an application for the development and variation of food regulatory measures in relation to GMOs or GM products, give written notice to the Regulator inviting written advice from the Regulator on the application. The Authority must then have regard to such advice in making an assessment of the application. The Authority is required to advise the Regulator of the nature of the recommendations

35 Department of the Parliamentary Library Bills Digest No 10 2000-01, Gene Technology (Consequential Amendments) Bill 2000, p.2.

36 Parliamentary Library, pp.2-3.

made to the Australia New Zealand Food Standards Council. The final decision of the Council is publicly notified in the Government Gazette. The decision, as it relates to GMOs or GM products, would then be entered on the Regulator's Record of GMOs and GM products.[37]

4.38 ANZFA is only required to give notice to the Regulator if the food regulatory measure relates to food which is or contains a GMO or a GM product. The effect of the changes to the *Australia New Zealand Food Authority Act 1991* is that food containing GM products will undergo the normal approval processes followed by ANZFA, including obtaining comments from the Regulator as well as other agencies. Food that is a GMO (such as sale of raw GM tomatoes) will be subject to the licensing regime prescribed in the Gene Technology Bill 2000, as well as to ANZFA's usual consultation and approval process. The manufacture of food containing GMOs may also be subject to licensing under the Gene Technology Bill 2000 in addition to approval by ANZFA.[38]

Industrial Chemicals

4.39 The Consequential Amendments Bill amends the *Industrial Chemicals (Notification and Assessment) Act 1989*. It would require the Director of Chemicals Notification and Assessment to consult the Regulator in relation to the assessment of, and application for, a permit for any industrial chemical that is or contains a GM product. As with agricultural and veterinary chemicals, the Director must give written notice to the Regulator that an application has been made involving a GM product, and seek the advice of the Regulator. The Regulator must provide written advice within a specified time period, and the Director must take that advice into account in making the ultimate decision on the application, and inform the Regulator of the decision. However, the Director is not obliged to follow any advice given by the Regulator.

4.40 The Director also has the ability to seek advice from the Regulator about an entire class of industrial chemicals containing a certain class of GM products If an advice from the Regulator about a class of GM products is in force, the Director does not need to seek advice from the Regulator in relation to applications for assessments and permits for industrial chemicals containing those GM products However, the Director still has to take the class advice into account in making individual decisions, and must notify the Regulator of each individual decision made.[39]

Therapeutic Goods

4.41 The Consequential Amendments Bill would require the Secretary of DHAC to consult the Regulator in relation to applications for registration or listing of any

37 Explanatory Memorandum.

38 Parliamentary Library, p.2.

39 Parliamentary Library, pp.3-4.

therapeutic good which is or contains a GM product. Consonant with the proposed amendments to the schemes for agricultural and veterinary chemicals and industrial chemicals, the Secretary must give written notice to the Regulator that an application has been made involving a GM product, and seek the advice of the Regulator. The Regulator then provides written advice within the specified time period. The Secretary must take that advice into account in making the decision whether to register or list the therapeutic good, and must inform the Regulator of the decision. However, the Secretary is not obliged to follow any advice given by the Regulator.

4.42 There is also a process for the Secretary to seek advice from the Regulator about an entire class of therapeutic goods containing a certain class of GM products which duplicates the amendments to the industrial chemicals scheme. If an advice from the Regulator about a class of GM products is in force, the Secretary does not need to request advice from the Regulator in relation to applications for registration or listing of therapeutic goods containing those GM products. However, the Secretary still has to take the class advice into account in making individual decisions, and notify the Regulator of each individual decision made.

Import of GMOs

4.43 GMOs are prohibited from being imported, and will therefore require a licence under the Gene Technology Bill, and as such, it is not also necessary to make them prohibited imports under the *Customs Act 1901*. In addition, AQIS will have to approve the import of any live viable organism.[40]

4.44 In relation to imported GMOs, the IOGTR stated that if the GMO was to be released into the environment, the GTR would have to assess the risks associated with that release and would require field trials – 'you could not ever import a live viable genetically modified organism into Australia and just start growing it or releasing it into the environment without field trials being conducted to assess any unique risks to the unique Australian environment'.[41] The IOGTR also stated that if a GMO was for processing food, for example, the GTR would have to assess the risks and approve the dealing but would not require field trials because the purpose of the import is for processing. AQIS would also have to approve the GMO import.[42]

Conclusion

4.45 The Parliamentary Library stated that the Consequential Amendments Bill does not alter the substance of the existing Commonwealth regulatory schemes in relation to food, therapeutic goods, agricultural, veterinary and industrial chemicals. The Bill merely adds an additional element to the existing structure of regulation, requiring advice from the Regulator to be sought and considered in relation to certain

40 IOGTR, Additional Information dated 11October 2000.

41 *Committee Hansard*, 14.8.00, p.32 (IOGTR).

42 *Committee Hansard*, 14.8.00, p.32 (IOGTR).

applications for products containing GMOs. The Regulator's advice on GM products used in all four areas is intended to provide some measure of consistency of treatment of GM products.[43]

4.46 Although provision is made for the Regulator to provide advice about a class of GM products in relation to both therapeutic goods and industrial chemicals, no such provision for class advice is made in relation to agricultural and veterinary chemicals. The Parliamentary Library stated that the reason for this omission is 'not immediately apparent'.[44] The Committee believes that this omission needs to be addressed in the legislation.

Advantages of a 'gap-filler' approach

4.47 The IOGTR stated that the Bill creates a 'one-stop shop' for biosafety assessment of all GMOs and GM products by establishing a centralised national regulator who undertakes risk assessment of all GMOs and GM products.[45]

4.48 The IOGTR stated that the advantages of this approach are that it:

- recognises the roles of each of the existing regulators, and the desirability of assessing GM products along with their non-GM counterparts under the relevant regulatory framework. For example, GM therapeutic goods are most appropriately assessed for safety, quality and efficacy under the therapeutic goods scheme, with advice on the safety aspects of the medicine associated with the genetic manipulation being provided by the Gene Technology Regulator;
- ensures that like products are treated in a similar way (reducing market distortions) while also ensuring that any risks posed by gene technology are considered in all cases;
- ensures that the GTR acts as a centralised area of expertise on genetic safety associated with gene technology who will make advice available to other regulators of GM products. This reduces costs to government by eliminating the need for each regulatory agency to establish a centre of expertise on gene technology;
- ensures that all aspects of production, manufacture, sale etc of GMOs and GM products are regulated and that there are no 'gaps' in regulatory coverage. The system also ensures that the GTR either directly regulates, or provides advice to other regulators, on all GMOs and GM products;
- minimises duplication by implementing strategies to improve the interface between regulators. For example, the legislation requires exchange of information between regulators; the GTR to hold a centralised database of all

43 Parliamentary Library, p.5.

44 Parliamentary Library, p.5.

45 Submission No.77, p.71 (IOGTR).

approvals for GMOs and for GM products approved in Australia (the Record of GMOs and GM product approvals); and the GTR to work with other agencies to harmonise data requirements, assessment and standards in relation to risks posed by gene technology; and

- is able to be implemented by 3 January 2001. A more complex single agency to regulate all GMOs and GM products would take significantly longer to establish and community and industry demand for a fully operational GTR by 2001 could not be met.[46]

Conclusion

4.49 The Committee believes that it is important that a comprehensive regulatory scheme be established to control the various dealings with GMOs and to provide a high level of reassurance to the community that any risks posed by the use of gene technology are minimised.

4.50 The Committee acknowledges that the proposed structure in the Bill establishes a regulatory regime that will interface with existing regulators. This option ensures that all aspects of the production, manufacture and sale of GMOs and GM products are regulated and that there are no 'gaps' in regulatory coverage. The system also ensures that the Regulator either directly regulates, or provides advice to other regulators, on all GMOs and GM products.

4.51 The Committee believes, however, that there may be significant benefits in introducing a 'one-stop shop' arrangement for business and the community generally. The Committee believes that this approach would ensure a more comprehensive regulation of all activities and dealings involving GMOs or GM products and a more streamlined assessment process. The Committee is, however, mindful that complete reform of existing systems and the establishment of a 'super-regulator' would also take considerable time and therefore believes that the option of introducing a 'one-stop shop' should be considered after an assessment has been made of the overall effectiveness of the proposed scheme and as part of the review of the scheme that the Committee has previously recommended should occur (see Chapter 3).

Recommendation

The Committee RECOMMENDS that as part of the review of the scheme as recommended by the Committee, the review consider the feasibility of introducing a 'one-stop shop' model having regard to the operational effectiveness of the proposed 'gap filler' arrangements.

46 Submission No.77, p.72 (IOGTR). See also IOGTR, Additional Information dated 18 September 2000.

Risk assessment processes

4.52 The Gene Technology Bill provides that, before issuing a licence, the Regulator must prepare a comprehensive risk assessment and risk management plan (sub-clause 50(1)). The risk assessment would:

- identify any hazards to public health and safety or the environment with the dealing, based on objective information;
- estimate the probabilities of hazards occurring; and
- estimate the risk that is a function of the above factors.[47]

4.53 'Risk assessment' is the process of determining and evaluating the potential risks posed by the dealings with a GMO, the magnitude of the risks and the probability of the risks occurring. For the purposes of the regulatory system for gene technology, the objective of risk assessment is to identify and evaluate the potential adverse effects of GMOs to the environment, or to human health. Risk assessment is followed by 'risk management', which is the identification of options and strategies to manage the risk.[48] The risk management plan may provide that the risks cannot be managed and, as such, a licence should not be granted. Alternatively, the plan could set out conditions that would be necessary for the risks to be effectively managed.

4.54 Whether or not there is significant risk in relation to the dealings proposed to be authorised by the licence, the Regulator must prepare a comprehensive risk assessment and risk management plan to manage any risks so as to protect the health and safety of people and the environment (sub-clause 50(2)).[49]

4.55 The Bill details a range of matters which must be considered by the Regulator in preparing the risk assessment. Those matters include the risks posed by the proposed dealings, submissions made to the Regulator, and any advice provided by the Gene Technology Technical Advisory Committee, and Commonwealth, State and local government agencies (sub-clause 51(1)).

4.56 In preparing the risk management plan, the Regulator must consider a range of matters including the means of managing any risks to the health and safety of people and the environment posed by the proposed dealing, submissions made to the Regulator, and any advice provided by the Gene Technology Technical Advisory Committee, the Commonwealth Environment Minister and Commonwealth, State and local government agencies (sub-clause 51(2)).

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47 Explanatory Memorandum, Gene Technology Bill 2000, p.63.

48 Submission No.77, pp.57-8 (IOGTR).

49 Explanatory Memorandum, p.63; Parliamentary Library, Bills Digest No 11 2000-01, Gene Technology Bill 2000, p.14.

4.57 After preparing the risk assessment and risk management plan, the Regulator must invite written submissions from the public on those documents. The Regulator must also seek advice on the risk assessment and risk management plan from the States, Gene Technology Technical Advisory Committee, the Commonwealth Environment Minister and Commonwealth authorities or agencies prescribed in the Regulations (clause 52). This issue is discussed further in Chapter 5.

4.58 The Regulator also has a discretion to take other action, such as hold public hearings (clause 53). Although the Regulator is required to take into account the advice given by these persons and bodies, he or she is not required to follow the advice given by any of them – the ultimate decision to issue a licence remains with the Regulator.[50]

Assessment processes in other Australian legislative schemes

4.59 The IOGTR stated that the proposed gene technology scheme will adopt a scientific risk assessment model not unlike those already in place for food, therapeutic goods and agricultural and veterinary chemicals.

4.60 The IOGTR noted that while other regulatory schemes have elements of a consultative process, the gene technology regulatory regime is the only scheme that provides two rounds of consultation on all high risk applications; enables public access to the full application provided by the applicant; sets out legislated criteria requiring consultation with the Environment Minister, Commonwealth agencies and States; establishes a statutory expert advisory committee to advise on all applications; sets out legislated criteria requiring the Regulator to take into account all advice received in relation to the application; and provides public access to details of the final decision on a consolidated database.[51] A table which compares the risk assessment processes of the existing regulatory systems is at Appendix 5.

Assessment processes in overseas countries

4.61 The IOGTR provided information on the assessment process provided for under the Bill compared to processes employed by overseas bodies in the United States of America, New Zealand, Canada, the European Community, the United Kingdom, Germany, Japan, South Korea, and South Africa.

4.62 The IOGTR stated that the following general comments may be made about the Bill in comparison to other countries:

- many other countries have utilised existing environment protection or plant legislation to regulate GMOs. For example, in both the UK and Canada, existing environment protection legislation is utilised, but with regulations made under the legislation specifically to deal with the release of GMOs into the

50 Parliamentary Library, p.15.

51 Submission No.77, pp.66-7 (IOGTR).

environment. Other countries such as Germany, Austria and South Africa have enacted specific legislation dealing with GMOs;

- of the countries examined, all distinguish between contained work and deliberate releases into the environment, with a more streamlined system of regulation applying in relation to contained work and a more detailed risk assessment being necessary in relation to deliberate releases into the environment. Many countries deal with contained work in separate legislation from that dealing with intentional release of a GMO into the environment;
- all the countries examined define GMOs slightly differently, consistent with the parameters of the legislation under which the GMO is regulated. For example, in Canada and New Zealand, GMOs are assessed as new substances, and in the United States GMOs are assessed according to whether they are, or have the potential to be, a plant pest. The advantage of the Australian system is that specific legislation has been developed to deal with GMOs and, as such, the scope of the legislation has been able to be defined broadly and all relevant matters allowed to be taken into account;
- in relation to the intentional release of a GMO into the environment – of the countries examined, all require the proponent to submit a detailed data package against information requirements set out by the competent authority. For example, the EC Directive in relation to deliberate releases of GMOs includes an annex describing the data which must be provided by the applicant. Similarly, the regulations developed under the Gene Technology Bill will set out data requirements. During consultations, a number of people emphasised the importance of harmonising Australian data requirements with those of other countries. As such, the regulations have been developed having regard to the data requirements of other countries;
- most countries have the capacity to draw on expert advice or seek public comment on applications. For example, in the UK, the relevant Minister seeks advice from the Advisory Committee on Releases into the Environment and in Germany the Federal Ministry for Health seeks advice from the Advisory Committee for Biological Safety. Similarly, some countries have the capacity to seek public comment on applications but this is not required in all cases. For example, the EC directive provides that member states may consult the public on any aspect of the application. To date, no other system has been identified that requires (in legislation) consultation with both an expert scientific committee and two rounds of public consultation on applications involving release of a GMO that may pose significant risks to the environment, as the Gene Technology Bill requires;
- in some countries, the approval to release a GMO into the environment may be subject to conditions, and in others, such as New Zealand and the United States, no conditions may be applied once an approval has been granted. During consultations on the Gene Technology Bill, stakeholders emphasised the importance of the GTR being able to impose conditions, where necessary, to

manage any risks posed by the GMO. A number of commentators on existing systems overseas have also emphasised the importance of being able to impose conditions, the Gene Technology Bill therefore provides for the imposition of any conditions that are necessary to manage risk;

- most countries have the capacity to appoint inspectors to enforce the legislation. For example, under general environment protection legislation in Canada, inspectors may be appointed to monitor compliance with the legislation, remedial action may be required and penalties may be imposed for breach of the legislation. Compared to other countries, the Australian Bill provides for significant monitoring, inspection and enforcement powers.[52]

Flaws in risk assessment processes

4.63 Several submissions and other evidence from environmental groups argued that the risk assessment framework provided for in the Bill is weak and needs to be significantly improved.[53]

Failure to incorporate the precautionary principle

4.64 Evidence from environmental and other groups argued that the Regulator should apply the precautionary principle in decision-making relating to GMOs, given the potential uncertainties and risks surrounding gene technology.[54] ACEL argued that:

> The precautionary principle should be the central foundation on which the entire regulatory superstructure of gene technology is built. The precautionary principle finds its basis in the principles of economically sustainable development which should also be taken into account by the Regulator in deciding whether to issue a licence. Adopting the precautionary principle, the Bill should require that the lack of full scientific certainty about risks entailed by activities or dealings involving gene technology cannot be used as a pretext for not taking measures or making decisions to prevent risks to health and safety, the environment or biological diversity.[55]

4.65 ACF GeneEthics Network argued that 'the principle is now enshrined in many international treaties and Australian laws, to ensure protection for the environment and

52 Submission No.77, pp. 69-70 (IOGTR).

53 *Committee Hansard*, 24.8.00, p.308 (ACF); Submission No.51, p.5 (Friends of the Earth (Fitzroy)); Submission No.40, p.4 (ACF).

54 *Committee Hansard*, 24.8.00, pp.305-6 (ACF); *Committee Hansard*, 25.8.00, p.357 (ACEL); Submission No.34, p.5 (ACEL); Submission No.51, p.4 (Friends of the Earth (Fitzroy)); Submission No.40, pp.1-2 (ACF); Submission No.54, p.6 (OFA); Submission No.85, p.7 (ACF GeneEthics Network); Submission No.6, pp.7-8 (Consumers' Association of SA).

55 Submission No.34, p.5 (ACEL).

public health. With a new technology capable of affecting all living organisms, such precaution is very appropriate and it has huge public support'.[56]

4.66 Submissions argued that the application of the precautionary principle under the Bill should provide that the Regulator should not issue a licence unless there is sufficient evidence that the activities or dealings involving gene technology pose no significant risk to health and safety, the environment or biological diversity. The submissions emphasised that in making the determination about risk, the precautionary principle requires extensive risk assessment using rigorous methodology.[57]

4.67 Submissions and other evidence from industry groups were opposed to incorporating the precautionary principle into the risk assessment process. Avcare Ltd stated that 'sound science must be used for risk assessment purposes. We do not subscribe to the proposition that the precautionary principle should be used for risk assessments…a precautionary approach should be applied to risk management'.[58] Avcare also noted that the Bill provides for the Regulator to take a cautious approach in making licensing decisions and that there is sufficient sound science available on which to grant a licence – 'if there is not, then a licence will not be issued'.[59]

4.68 Avcare also stated that there 'are about 12 different definitions of the precautionary principle, and there has not been an agreement yet what a universal definition should be'.[60] Avcare also commented that 'very few' overseas countries have the precautionary principle spelt out in their legislation.[61]

4.69 The IOGTR stated that the Commonwealth and the States agreed that the risk assessment and management process outlined in the proposed legislation embodied a *precautionary approach*.[62] The IOGTR further stated that:

> …rather than explicitly referencing the Precautionary Principle and potentially creating uncertainty about its interpretation, all jurisdictions agreed it was better to provide clear directions to the Gene Technology Regulator about how to apply precaution in considering each application. Debate on the adequacy of the legislation should therefore focus on the adequacy of the risk assessment and management process in the legislation

56 Submission No.85, p.7 (ACF GeneEthics Network).

57 Submission No.34, p.5 (ACEL); Submission No.51, pp.4-5 (Friends of the Earth (Fitzroy)); Submission No.85, p.7 (ACF GeneEthics Network).

58 *Committee Hansard*, 25.8.00, p.381 (Avcare Ltd).

59 Submission No.32, p.4 (Avcare Ltd).

60 *Committee Hansard*, 25.8.00, p.381 (Avcare Ltd).

61 *Committee Hansard*, 25.8.00, p.381 (Avcare Ltd).

62 Submission No.77, p.74 (IOGTR).

rather than be misdirected into argument about the interpretation of the Precautionary Principle.[63]

Conclusion

4.70 The Committee believes that given the potential risks and uncertainties associated with gene technology the Bill needs to be amended to provide clear directions to the Regulator about how to apply precaution when considering licence applications. The issue of the precautionary principle is further discussed in Chapter 3.

Recommendation

The Committee RECOMMENDS that the Objects of the Bill contain the same words that appear in the *Environment Protection and Biodiversity Conservation Act 1999* in relation to the Precautionary Principle.

Referral to the Environment Minister

4.71 As noted above, the Bill only requires that the Regulator 'seek advice' from the Environment Minister in preparing risk assessment and risk management plans for intentional releases of GMOs into the environment (sub-clause 50(3)).

4.72 Submissions and other evidence from environmental and other groups argued that this is a significant dilution of any requirement to conduct an environmental impact assessment (EIA) under the proposed consequential amendments to the *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act).[64] In January 2000 the Environment Minister released a draft proposal for consultation whereby the EPBC Act would be amended to provide for the environmental assessment of GMOs. This provision was contained in the first Gene Technology (Consequential Amendments) Bill 2000 released in late January 2000.

4.73 These amendments would have introduced a new Part 4A to the EPBC Act – 'Special Rules for GMOs'. The proposed Part 4A would have required the referral of releases of GMOs to the Minister for the Environment and Heritage ('Environment Minister') for environmental assessment pursuant to the EPBC Act.

4.74 Under the proposed amendments to the EPBC Act, the Gene Technology Regulator would refer certain applications for a GMO licence under the Gene Technology Bill to the Minister for the Environment and Heritage. All applications involving a deliberate release of a GMO into the environment would be referred to the Environment Minister. Proposed GMO dealings which do not include a deliberate

63 Submission No.77, p.74 (IOGTR); IOGTR, Additional Information dated 18 September 2000. See also *Committee Hansard,* 25.8.00, p.381 (Avcare Ltd).

64 Submission No.86, p.1 (WWF & HSI); Submission No.69, p.3 (Friends of the Earth (Perth, WA Group)); Submission No.34, pp.5-6 (ACEL); Submission No.40, p.2 (ACF); Submission No.50, p.6 (Consumer Food Network); *Committee Hansard,* 24.8.00, pp.306-7, 328-9 (ACF); *Committee Hansard,* 25.8.00, pp.358, 367, 373-4 (ACEL).

release into the environment but which pose a significant risk of harm to the environment would also be referred.

4.75 Upon receiving a referral, the Environment Minister would determine whether the broader risk assessment process being carried out by the Gene Technology Regulator is adequate to ensure a full assessment of environmental risks and, if not, what further environmental assessment under the EPBC Act is to be carried out.

4.76 The proposed GMO dealing would be subject to the assessment provisions of the EPBC Act (Part 8 of the EPBC Act). Under Part 8 of the EPBC Act (as applied), there are various assessment options available to the Environment Minister. For example, if the risk assessment process being undertaken by the Gene Technology Regulator is adequate in relation to a particular proposal, then the Environment Minister can accredit that process. If further assessment is required, the Environment Minister can direct the preparation of, for example, an EIS.[65]

4.77 The draft amendments were intended to ensure that any environmental assessment process under the EPBC Act would, to the greatest extent possible, be effectively integrated with the broader risk assessment process carried out by the Regulator under the Gene Technology Bill. This would ensure a rigorous and efficient assessment process that avoids unnecessary duplication and delay.

4.78 After the environmental assessment is conducted, the Environment Minister would provide advice to the Gene Technology Regulator. The Gene Technology Regulator would take this advice into account before making a licence decision and would report to the Minister on how the environmental advice was dealt with.

4.79 The IOGTR stated that following consultation on the proposal to amend the EPBC Act, the States, Territories and the Commonwealth considered that the objectives of the proposed amendments 'could be better met by providing for comprehensive assessment of environmental risks, through the Gene Technology Bill rather than through amendments to the EPBC Act'.[66]

4.80 The World Wide Fund for Nature (WWF) and the Humane Society International (HSI) stated that the proposed amendments to the EPBC Act have a number of benefits, in that it ensures rigorous environmental assessment and input by the Environment Minister; and that there is only one process, administered by the Regulator, and one approval, from the Regulator.[67]

4.81 Submissions stated that risk assessment, as proposed under the Gene Technology Bill, is no substitute for a detailed EIA. ACEL argued that:

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65 *Environmental Assessment of Genetically Modified Organisms – Draft Amendments to the EPBC Act 1999.*

66 IOGTR, Additional Information dated 18 September 2000.

67 Submission No.86, Addendum (WWF & HSI).

> …while risk analysis and assessment can produce information on one aspect of a proposal, EIA is capable of bringing together information on a variety of aspects. The simple fact is that an EIA is much more comprehensive than risk assessment can be, and by jettisoning EIA requirements, the *GTB* 2000 jeopardises not only public health and safety, but also Australia's unique environment, its myriad ecosystems and mega-biological diversity. Indeed, risk assessment does not ordinarily entail consideration of the environment apart from its potential effects on human health and safety.[68]

4.82 ACEL also argued that by failing to include the EIA trigger under the EPBC Act 'the probability that harm to humans or damage to the environment will be caused by gene technology is greatly increased because it is much more likely that something will be overlooked'.[69] WWF & HSI also argued that without the provision of an EIA under the EPBC Act the Bill 'will not achieve its object of protecting the environment'.[70]

4.83 Some submissions argued that the Environment Minister should have an even stronger role in the regulation of GMO releases. The EPBC Act currently provides that actions which are likely to have a significant impact on one of the defined matters of 'national environmental significance' (for example, nationally threatened species) will require approval from the Minister for the Environment and Heritage. Submissions argued that the EPBC Act should be amended to include the release of GMOs into the environment as a 'matter of national environmental significance'. This would ensure that where there is the potential for a GMO release to have a significant impact on the environment, full environmental assessment would occur under the EPBC Act. It would also go further than the earlier proposal, by giving the Environment Minister power to veto any GMO releases if the risks were considered too great.[71]

Conclusion

4.84 The Committee believes that the success of the new regulatory system will in part depend on ensuring that there is a single process through which applications must pass. The Committee has discussed the advantages of this approach in relation to the proposed structure of the OGTR (see earlier discussion).

4.85 The Committee does, however, believe that the Environmental Impact Assessment as outlined in the EPBC Act has merit and provides for a comprehensive approach to safeguard the environment from the potential risks posed by gene technology. Rather than have two separate processes, the environmental provisions in the Gene Technology Act and regulations should closely parallel the procedures in the EPBC Act.

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68 Submission No.34, p.6 (ACEL).

69 Submission No.34, p.6 (ACEL).

70 Submission No.86, p.1 (WWF & HSI). See also Submission No.85, p.8 (ACF GeneEthics Network).

71 Submission No.86, p.2 (WWF & HSI); Submission No.85, p.8 (ACF GeneEthics Network).

4.86 If this is done, the Committee does not see a need for the Environment Minister to have a veto on the release of GMOs. It believes that the ultimate authority for approval of applications should rest with the Regulator.

Recommendation

The Committee RECOMMENDS that in preparing risk assessment and risk management plans for the intentional release of GMOs into the environment, the Regulator be required to follow a process that should be no weaker than the Environmental Impact Assessment process set out in the *Environment Protection and Biodiversity Conservation Act 1999.*

Other inadequacies in the risk assessment process

4.87 Submissions argued that there several other inadequacies relating to risk assessment processes in the Bill.

Risk assessment – matters to be taken into account

4.88 The Australian Conservation Foundation (ACF) argued that there is no requirement that the risk assessment include consideration of the potential impacts on the environment posed by the dealings (clause 51). ACF argued that the Regulator should be required to consider a range of factors when preparing the risk assessment of any dealings with GMOs, including all relevant scientific evidence; the general characteristics of both the GMO or product and the parent organisms; the native environments of the recipient organism and donor organism; the intended use(s) of the GMO or product; potential impact of the GMO or product on the environment; effects of the GMO or product on human, plant and animal health; socio-economic impacts; conformity with ethical norms; and details of risk assessments completed elsewhere.[72]

4.89 The IOGTR stated that the Bill is not prescriptive about the specific tasks that the Regulator must consider as part of the risk assessment process – this was intentionally excluded from the Bill because there are many different types of GMOs that the Regulator will be examining, and the Regulator will need flexibility to examine any risks posed by the proposed dealings with the particular GMO. However, some broad categories of risk have been prescribed in the Regulations to be taken into account by the Regulator. For example, the Regulator must take into account:

- any previous assessment, in Australia or overseas, in relation to allowing or approving dealings with the GMO; and
- the potential of the GMO to be harmful to other organisms; adversely affect any ecosystems; transfer genetic material to another organism; have selective

72 Submission No.40, pp.4, 9-13 (ACF).

advantage in the natural environment; spread or persist in the environment; and be toxic, allergenic or pathogenic to human beings.[73]

4.90 The IOGTR stated that it is currently working on other criteria that the Regulator must take into account in preparing a risk assessment and risk management plan and that will be subject to further public consultations.[74]

4.91 The Committee believes that several of the concerns of environmental groups have been addressed by the regulations in relation to matters to be taken into account in risk assessment plans. The Committee considers that other criteria, yet to be developed, that the Regulator must take into account in preparing risk assessment plans should also be prescribed in the regulations.

Recommendation

The Committee RECOMMENDS that a complete listing of broad categories of risk that the Regulator must consider as part of the risk assessment and risk management plans, be prescribed in the regulations to the Bill.

Level of risk

4.92 Environmental groups also noted that when preparing risk assessment and risk management plans for dealings not involving the intentional release of a GMO into the environment, the Regulator need consider fewer matters than would be required if the dealing involved the release of a GMO into the environment. Several groups argued that the Regulator should be required to consider the same matters when preparing risk assessment and risk management plans for dealings not involving the intentional release of a GMO into the environment as would be required if the dealing involved the intentional release of a GMO into the environment.[75]

4.93 The IOGTR noted, however, that the proposed regulatory regime is based on a system whereby the level of regulation applied to particular dealings with GMOs is commensurate with the level of risk posed by the particular dealings.[76] The Interim Office also noted that overseas countries distinguish between contained work and deliberate releases into the environment, with a more streamlined system of regulation applying in relation to contained work and a more detailed risk assessment being necessary in relation to deliberate releases into the environment.[77]

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73 Explanatory Guide to the Draft Commonwealth Gene Technology Regulations 2000, August 2000, pp.25-6.

74 Explanatory Guide to the Draft Regulations, p.26.

75 Submission No.40, pp.3-4 (ACF); Submission No.51, p.5 (Friends of the Earth (Fitzroy)).

76 Submission No.77, p.59 (IOGTR).

77 Submission No.77, p.69 (IOGTR).

4.94 The Committee believes that the approach proposed in the Bill whereby the level of regulation applied to particular dealings with GMOs is commensurate with the level of risk posed by the particular dealings is appropriate.

Insurance coverage

4.95 A further issue raised by environment groups was that there is no requirement for the Regulator to consider whether the applicant has access to insurance coverage for the proposed GMO dealing. These groups argued that the Regulator should determine whether insurance is available to cover the risks associated with the dealings for which the licence has been applied. Furthermore, the lack of insurance coverage should constitute prima facie evidence that the risks are too high or uncertain for the licence to be issued.[78] This issue is discussed further in Chapter 6.

4.96 The Committee believes that in setting licence conditions, the Regulator should satisfy him or herself that applicants have made provision for suitable insurance coverage to cover the risks associated with the dealings.

Recommendation

The Committee RECOMMENDS that the Bill be amended to require that in prescribing or imposing conditions of licences, the Regulator may satisfy him or herself that applicants have made provision for suitable insurance coverage to cover the risks associated with the dealings.

Confidential commercial information

4.97 The Bill provides that a person may apply to the Regulator for a declaration that certain information is confidential commercial information (clause 184). The Regulator is obliged to declare information to be confidential commercial information if it is:

- a trade secret;
- information with commercial or other value which would be destroyed or diminished by disclosure; or
- information about the commercial or financial affairs of an organisation or person if disclosure would unreasonably affect that person or organisation (clause 185).

4.98 However, the Regulator has a discretion to refuse to declare the information confidential commercial information if, in the Regulator's opinion, the public interest in disclosure would outweigh the prejudice (sub-clause 185(2)).

4.99 Environs Kimberley stated that:

78 Submission No.34, p.5 (ACEL); Submission No.40, p.4 (ACF); Submission No.51, p.5 (Friends of the Earth (Fitzroy)).

> The phrase "commercial in confidence" has an extremely wide meaning in the Act (clause 184) and at common law, and it is well known that it is used as a mechanism to prevent legitimate public inquiry into matters that may, or have, harmed the public or the environment.[79]

4.100 Environs Kimberley further stated that although sub-clause 185(2) provides scope for the Regulator to disregard this assessment of confidential commercial information when disclosing information concerning GMOs, 'this does not necessarily deal with the potential breadth of information hidden by this clause'.[80] The Parliamentary Library also noted that it seems likely that a broad range of information in applications for research and development in new gene technology would encompass 'trade secrets' and 'commercial information' under the Bill.[81]

4.101 The Parliamentary Library also commented that there are significant limitations on the use of confidential commercial information. Such information:

- cannot be disclosed in the information provided to the public during the community consultation on GMO licence applications (clause 54);
- cannot be used by the Regulator in considering other GMO licence applications, unless the information owner gives written consent (clause 45). The clause is intended to combat the 'free rider' effect, where it would be possible for a second applicant to minimise the resource implications of a licence application by referring to, or using, information already made available to the Regulator in support of another application; and
- is not recorded on the Record of GMO and GM Product Dealings (sub-clauses 138(3), (4), and (5)).[82]

4.102 The Committee believes that the Bill needs to strike a balance between the protection of confidential information and the need for a high level of transparency of the regulatory regime. This issue is discussed in Chapter 3.

Powers and investigative capability of the Regulator

4.103 The Bill provides a number of provisions to enforce compliance with the legislation. The relevant provisions relate to:

- imposition of conditions;
- monitoring of compliance with conditions;
- reporting obligations;

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79 Submission No.82, p.7 (Environs Kimberley). See also Submission No.35, p.9 (GE-Free Tasmania); Submission No.69, p.2 (Friends of the Earth (Perth, WA Group)).

80 Submission No.82, p.7 (Environs Kimberley).

81 Parliamentary Library, p.24.

82 Parliamentary Library, p.24. See also Explanatory Memorandum, p.61.

- powers to investigate alleged breaches;
- enforcement powers; and
- penalties.

Imposition of conditions

Licences issued by the GTR may be subject to four different types of conditions. These are conditions:

- set out in the Bill - there are currently three such conditions described in clauses 63, 64 and 65. These statutory conditions require all licence holders to:
    - inform anyone covered by a licence of the conditions that relate to them. This is a minimum requirement. Conditions applied on a case-by-case basis may set out exactly how such people are to be informed (for example, through labelling, training etc.);
    - allow the GTR, or a person authorised by the GTR, to enter premises for the purposes of auditing and monitoring; and
    - inform the GTR of any additional information that becomes available regarding risks to public health and safety and the environment or contraventions of the legislation.
- prescribed by the Regulations;
- imposed by the GTR at the time of issuing the licence. The GTR may impose any conditions that are necessary to manage risk, as assessed on a case-by-case basis. The GTR may limit where the GMO is used, who uses the GMO and how it is used. For example, the GTR may require specific containment measures, waste disposal methods and reporting requirements; and
- imposed by the GTR after the licence is issued.[83]

Burden of proof

4.104 ACEL argued that given the potential risks associated with the use, application or release of GMOs, it is imperative that the regulatory framework clearly establishes that the applicant for a licence bears the burden of proof in connection with an application for a licence.[84]

4.105 In particular, ACEL maintained that the applicant should be required to demonstrate beyond reasonable doubt that granting the application will not result in damage or harm to human health or to the environment.[85] ACEL commented that

83 Submission No.77, pp.83-4 (IOGTR).

84 Submission No.34, p.7 (ACEL); *Committee Hansard*, 25.8.00, pp.369-70 (ACEL).

85 Submission No.34, p.7 (ACEL); *Committee Hansard*, 25.8.00, pp.369-70 (ACEL).

'imposing that sort of burden is like making somebody prove a negative. It is not done very often. It is very difficult to prove. Maybe it is not entirely appropriate for every application, but it certainly is appropriate where there is likely to be a significant impact on the environment'.[86]

4.106 The Committee agrees that it is the primary responsibility of the applicant to provide adequate scientific support for its case to the Regulator. However, in order to maintain credibility, the Regulator is obliged to make his or her decision based on independent assessment and evaluation of data provided by the applicant and through the public and committee processes.

4.107 In addition, the Regulator needs to be able to commission additional independent research and undertake monitoring to satisfy any concerns. The Committee believes that for an applicant to bear the sole burden of proof would in fact compromise the perceived indpendence of the Regulator and limit his or her ability to make decisions on a wide range of information.

Exemptions to the licensing system

4.108 Certain dealings with GMOs are not subject to the licensing system. Exempt dealings, dealings listed on the GMO Register and notifiable low risk dealings will be able to be conducted without going through the licensing system.

4.109 Exempt dealings are exempt from the requirements of the legislation on the basis of the negligible risk posed by the dealing with the GMO. Exemptions are prescribed in the Regulations (Part 1 of Schedule 1).[87] The exemptions in the Regulations are based on the current exemptions in the GMAC Guidelines for Small Scale Genetic Manipulation Work. The GMAC exemptions have been developed over the last 25 years, based on the experience of assessing applications in Australia. The exemptions apply to a very limited number of dealings with GMOs that:

- have been assessed over time as presenting no significant biosafety risks to public health and safety, including occupational health and safety, or the environment; and
- are undertaken within contained facilities, that is, they do not involve intentional release of a GMO into the environment.[88]

4.110 The IOGTR stated that the dealings with GMOs that are included on the list of exemptions will be reviewed regularly. In addition, any member of the public may, at any time, make a submission to the GTR proposing that certain dealings with GMOs be removed from the list of exemptions, or be included on the list of exemptions.

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86 *Committee Hansard,* 25.8.00, p.370 (ACEL).

87 Explanatory Guide to the Draft Regulations, p.22. Exempt GMOs are those that are set out in Part 1 of Schedule 1 of the Regulations.

88 Explanatory Guide to the Draft Regulations, p.39.

Before making changes to the list of exemptions, the GTR will undertake a full analysis of any risks posed by the dealings to determine whether they are justified in being removed from, or added to, the list of exemptions.[89]

4.111 Dealings listed on the GMO Register will be exempt following a period of licensing, monitoring of any risks and a determination that the GMO no longer requires licensing based on the absence of risk. Notifiable low risk dealings will be exempt on the basis that the work is to occur within a contained facility and does not present any significant risks. Notifiable low risk dealings are prescribed in the Regulations and will rely on self-assessment by researchers with the assistance of Institutional Biosafety Committees.[90] The Regulator, will, however, provide independent oversight of assessments.[91]

4.112 Submissions and other evidence argued that in some cases the requirement to obtain a licence may be circumvented if the proposed dealing falls within the blanket exemptions provided to dealings that are declared exempt dealings, dealings listed on the GMO Register and notifiable low risk dealings. As noted previously, dealings included on the GMO Register will be exempt following a period of licensing, monitoring of any risks and a determination that the GMO no longer requires licensing based on the absence of risk. The submissions argued that the blanket exemptions should be removed from the Bill so that all uses of GMOs should require a licence.[92]

4.113 The IOGTR argued that the Bill recognises that different types of dealings with GMOs present varying levels of risk, and that different levels of assessment and regulatory oversight are appropriate in relation to each.[93] The Interim Office noted that to remove the exemptions or the notifiable low risk dealings from the Bill would lead to the 'ludicrous situation' whereby very low risk activity would be required to undergo the comprehensive licensing process.[94]

4.114 The Committee believes that that the proposed system of exemptions should be retained in the Bill. The Committee does not consider that all dealings with GMOs should be subject to the same level of regulation and considers that the proposed regulatory regime recognises that different types of dealings with GMOs present varying levels of risk and that low risk dealings can be exempt.

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89 Explanatory Guide to the Draft Regulations, p.39.

90 Explanatory Guide to the Draft Regulations, pp.27-8.

91 Submission No.77, p.75 (IOGTR).

92 Submission No.40, p.5 (ACF); Submission No.51, p.11 (Friends of the Earth (Fitzroy)); *Committee Hansard*, 24.8.00, p.308 (ACF).

93 Submission No.77, pp.75-6 (IOGTR).

94 Submission No.77, p.76 (IOGTR).

Review of licences

4.115 Some submissions argued that the Bill should include requirements for the review or renewal of licences. The Bill provides that a licence remains valid either until the end of a specified period, or until it is cancelled or surrendered (clause 60). ACEL argued that it is unacceptable that licences will be issued in perpetuity without an established system for review or renewal. The Centre stated that review and renewal procedures are common in licensing regimes across Australia.[95] ACEL argued that the review should take place after three years, whereas ACF argued that a licence should not exceed a five year duration without renewal.[96]

Recommendation

The Committee RECOMMENDS that the Bill be amended to include provisions for the mandatory review or renewal of all licences granted by the Regulator; and that this review or renewal take place at intervals of not more than three years.

Buffer zones

4.116 The Bill does not set specific buffer zones around GM crops to protect organic and GM-free crops growing nearby. The Organic Federation of Australia (OFA) argued that the Regulator should be required to impose conditions to ensure that protection of the right to farm GM free is maintained by limiting pollen flow through the application of buffer zones and strict handling controls. OFA argued that the Regulator should not issue a licence for the release of a GMO without conditions that ensure that contamination of GM-free produce or land cannot occur.[97]

4.117 The IOGTR stated that the Regulator may set conditions to limit the dissemination or persistence of the GMO or its genetic material in the environment (clause 62). For example, the Regulator may require licence holders to establish buffer zones and the like to prevent contamination of non-GM crops.[98] The Parliamentary Library also commented that the Regulator will have power to impose conditions to limit contamination. It will be up to the Regulator whether it does so, and the level of stringency required, although the Regulator must be satisfied that any risks to the environment or to human health and safety can be adequately managed (sub-clause 56(1)). The Regulator also has power to vary a licence, including imposing additional conditions or removing or varying existing conditions. The Regulator cannot vary a licence for contained dealings to authorise the intentional

95 Submission No.34, p.12 (ACEL).

96 Submission No.34, p.12 (ACEL); Submission No.40, p.4 (ACF). See also Submission No.51, p.5 (Friends of the Earth (Fitzroy)).

97 Submission No.54, p.9 (OFA); *Committee Hansard*, 23.8.00, p.150 (OFA).

98 IOGTR, Additional Information dated 25 August 2000.

release of a GMO, and must be satisfied that any variations to the licence enable risks to be managed adequately (clause 71).[99]

4.118 The IOGTR also noted that there other mechanisms within the legislation to protect GM-free status of crops from potential contamination from GM crops. The legislation provides that the Regulator must not act inconsistently with policy principles issued by the Ministerial Council. So, if the Ministerial Council decided to make a policy principle, for example, to 'protect the diversity of Australian farming systems' the Regulator would have to make sure that appropriate conditions were put in place to give effect to this. The legislative framework also works under the assumption that all applications for dealings involving the intentional release of a GMO into the environment should be made publicly available, subject to limited exemptions for legitimately confidential commercial information.[100]

4.119 The Committee believes that the regulatory regime needs to ensure that the strictest controls are in place to ensure that organic farms and other non-GM farming systems are not subject to contamination by genetically modified crops. The Committee considers that the Regulator should not issue a licence for the release of a GMO without stringent conditions to ensure, as much as possible, that contamination of GM-free produce or land cannot occur.

Recommendation

The Committee RECOMMENDS that the Bill be amended to require that the Regulator not issue a licence for the release of a GMO without conditions that ensure, as much as possible, that contamination of non-genetically modified produce or land cannot occur.

Monitoring of compliance with conditions

4.120 The legislation provides the capacity for the GTR to monitor compliance with the legislation in a range of ways. The GTR may:

- require regular auditing to be undertaken by a licence holder and the results of such auditing to be reported to the GTR;
- undertake routine audits of a licence holder. This may involve notifying the licence holder and undertaking site inspections or 'on-site' audits of paperwork demonstrating compliance with conditions of licence. As currently occurs under the interim arrangements, the GTR will prepare a monitoring plan which ensures that the GTR undertakes site inspections at times when the risks posed by the GMO may be greatest and compliance with conditions of licence is most critical (for example, when GM crops are flowering); and

99 Parliamentary Library, pp.16-17.

100 IOGTR, Additional Information dated 25 August 2000.

- undertake 'on-the-spot' inspections or audits of dealings with GMOs. As detailed above, it is a statutory condition of licence that a licence holder must allow the GTR, or a person authorised by the GTR to enter premises for the purposes of auditing or monitoring the dealing. This enables the GTR, or his/her delegate to undertake inspections without providing prior notice to the licence holder.[101]

Auditing processes

4.121 Submissions argued that that the monitoring and auditing processes (clause 64) are inadequate, as there is no stipulation as to how often such monitoring or auditing should take place or the extent to which this should take place.[102] ACF argued that it should be a condition of a licence that a licence holder must monitor and evaluate, on a continuing basis after the licence is issued, any risks associated with the activities or dealing involving GMOs that are subject to the licence. ACF also argued that it should be a condition of a licence that licence holders must submit annual reports to the Regulator in respect of this monitoring.[103] The IOGTR stated that at a minimum, it is anticipated that all licence holders will be required to report annually, however the GTR may on a case-by-case basis determine that more regular auditing and reporting is necessary based on the level of risk posed by the dealings with the GMO.[104]

4.122 The licence-holder has a statutory obligation to inform the Regulator of any additional information as to risks, any contravention of the licence or any unintended effects of the dealings, that he or she becomes aware of (clause 65). If a GMO licence contains a particular condition relating to monitoring or auditing, persons authorised by the licence have an obligation to allow the Regulator into premises, to undertake such auditing or monitoring (clause 64).[105]

4.123 The Parliamentary Library stated that GMO licences may also contain conditions requiring licence holders to conduct regular monitoring, conduct periodic reviews of risk monitoring plans, or undertake sampling and testing to check for unintended environmental effects, however, 'these conditions are not legislatively required under the Bill, but may be imposed on a licence holder at the discretion of the Regulator'.[106]

4.124 The Parliamentary Library noted that the Bill provides for monitoring through random inspections and an obligation on licence-holders to report any breaches of the licence or unintended effects (Part 11 and clause 65). However, comprehensive

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101 Submission No.77, p.84 (IOGTR).

102 Submission No.51, p.6 (Friends of the Earth (Fitzroy)); Submission No.40, pp.4-5 (ACF).

103 Submission No.40, pp.4-5 (ACF).

104 Submission No.77, p.84 (IOGTR).

105 Parliamentary Library, p.23.

106 Parliamentary Library, pp.23, 41.

independent auditing to ensure compliance with licence conditions is not required unless it is made a condition of the GMO licence.[107] The Parliamentary Library further stated that:

> There is no provision in the Bill for a comprehensive independent auditing process to check the quality assurance systems being used by the licence-holder, and ensure the licence conditions and risk management plans are being followed.[108]

4.125 The Committee believes that that the monitoring and auditing processes in the Bill need to be strengthened. The Committee considers that a licence holder should be required, as a condition of a licence, to monitor any risks associated with the activities or dealing involving GMOs. The Committee also considers that as a condition of a licence, an independent audit of a licence holder should be undertaken by the Regulator to ensure compliance by the licence holder with the conditions of his or her licence.

Recommendations

The Committee RECOMMENDS that as a condition of a licence, a licence holder be required to monitor, on a continuing basis, any risks associated with the activities or dealing involving GMOs that are subject to the licence and the results of such monitoring be reported annually to the Regulator.

The Committee RECOMMENDS that as a condition of a licence, a licence holder be required to submit to an independent audit of his/her activities by the Regulator to ensure compliance with licence conditions.

Investigation of alleged breaches

4.126 The legislation enables the Regulator to appoint inspectors for the purposes of investigating alleged breaches of the legislation (clause 150).

4.127 The IOGTR stated that the investigation of breaches is a serious matter that is dealt with quite separately in the legislation from the general monitoring powers of the GTR. This is because if a breach of the legislation has been alleged, care needs to be taken not only to ensure that any evidential material (that will assist with a prosecution) is not lost but also to ensure that inspectors do not trespass unduly on personal rights and liberties.[109]

4.128 In the event of non-compliance with the conditions imposed, the legislation describes a range of investigative powers that may be used by inspectors appointed under the legislation for determining whether a breach has in fact occurred. These

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107 Parliamentary Library, p.30.

108 Parliamentary Library, p.23.

109 Submission No.77, p.85 (IOGTR).

powers include search powers, seizure powers and emergency powers (clauses 153,154,155).

4.129 The IOGTR stated that the inspection powers described in the legislation are similar to those of the Australian Federal Police, Customs agents and inspectors appointed under the Therapeutic Goods Act. The powers of inspection are 'significant' and are consistent with Commonwealth criminal law policy.[110]

Inspectors

4.130 Several submissions argued that sufficient funding must be provided for the employment of suitably qualified inspectors to enforce the compliance provisions of the Bill.[111] AFGC stated that 'it will be the number, independence and calibre of inspectors that will prove the adequacy of the inspectorial powers and inspectorial system'.[112]

4.131 The Committee believes that the problems with the Mt Gambier contamination issue is testament to the importance of strict enforcement of compliance with licence conditions to ensure consumer confidence in the regulatory system.

Recommendations

The Committee RECOMMENDS that suitably qualified inspectors be employed by the Regulator to enforce the compliance provisions in the Bill.

The Committee RECOMMENDS that the Regulator fund the employment of adequate numbers of inspectors to provide for sufficient frequency of inspection to act as a deterrent to non-compliance.

Enforcement powers

4.132 The Bill describes a range of enforcement powers available to the GTR. The Regulator may:

- vary conditions of licence to require a licence holder to take any further actions that are necessary;
- suspend or cancel a licence (which may necessitate the recall of the GMO or the cessation of any dealings with the GMO);
- seek an injunction from the Federal Court to restrain a person from continuing to engage in certain activities that are in breach of the legislation; and

110 Submission No.77, pp.84-5 (IOGTR).

111 Submission No.17, p.3 (NGAA); Submission No.102, p.4 (CSIRO).

112 Submission No.71, p.13 (AFGC).

- issue directions to the licence holder, or person covered by the licence, requiring the person to take any necessary steps to comply with the Act.[113]

4.133 As noted above, the Regulator has power to suspend or cancel a licence for a number of reasons. These include, if the Regulator:

- believes on reasonable grounds that the licence-holder or the person covered by the licence has breached a condition of the licence, including by not providing additional information to the Regulator;
- believes on reasonable grounds that the licence-holder or the person covered by the licence has committed an offence against the Bill or the Regulations; or
- becomes aware of risks which the licence-holder is not in a position to deal with adequately (clause 68).

4.134 If a licence holder or a person covered by a licence does not act in accordance with the legislation, and their actions are likely to cause, or are causing, harm to the health and safety of people or to the environment, then the GTR may give written directions to the person directing them to comply with the legislation. If the person does not take the necessary action within a specified period of time, the GTR may take additional steps, or direct that necessary steps be taken, to ensure compliance with the legislation. This provision effectively enables a 'clean-up' or remediation to be undertaken, either by the GTR or by the licence holder under the direction of the GTR.

4.135 The legislation further provides that if costs are incurred by the GTR in taking steps to bring the activity back into compliance with the legislation, such costs may be recovered from the licence holder or the person covered by the licence (as applicable).

4.136 The legislation also enables an inspector to take immediate action where there is an imminent risk of danger to health and safety of people or to the environment. In such circumstances, the inspector can take such steps as are necessary without first giving written notice to the licence holder or applicant requiring them to take the necessary steps. Such action, by the inspector or others, is also cost recoverable from the offending party.[114]

Offences and penalties

4.137 A holder of a GMO licence is guilty of an offence if they do something, or fail to do something, that results in a breach of a condition of licence. A similar offence exists for persons covered by a GMO licence who do something, or fail to do something, which results in a breach of a condition of licence.

113 Submission No.77, p.85 (IOGTR).

114 Submission No.77, p.85 (IOGTR).

4.138 There are a range of offences associated with a breach of a condition of licence that may be pursued depending on the circumstances of the particular case:

- in the case of a less serious or technical breach – the prosecution would just need to establish that the licence holder took action (or failed to take action) and that contravened the licence. In such a case a penalty could be imposed without the need to establish any 'mental element' of knowledge or recklessness. In this case, a penalty of up to 50 penalty units may be imposed. This equates to $5 500 for an individual and $27 500 for a corporation;
- in the case of a serious offence - the prosecution would need to establish that the licence holder or the person covered by the licence, intentionally took an action (or failed to take an action) that they knew (or they were reckless as to knowing) contravened a condition of licence. A larger penalty (500 penalty units) could then be imposed. This equates to $55 000 for an individual and $275 000 for a body corporate; or
- in the case of a breach of condition that causes significant damage, or is likely to cause significant damage, to the health and safety of people or the environment, two alternative penalties may be pursued:
    - if the prosecution can establish knowledge or recklessness a penalty of up to 2000 penalty units may be imposed. ($220 000 for an individual and $1.1 million for a body corporate).
    - if the prosecution pursues a strict liability offence (in these instances knowledge or recklessness does not have to be shown) then the penalty is 200 penalty units which equates to $22 000 for an individual and $110 000 for a corporation.[115]

4.139 The IOGTR stated that the draft Bill that was circulated in late 1999, did not include provision for 'tiered' offences or for strict liability offences. The need for strict liability offences and flexibility to respond to different types of breaches, was pointed out during consultations. The Bill was therefore amended to reflect these concerns.[116]

4.140 The IOGTR stated that the offence provisions, and the accompanying penalties in the Bill are consistent with criminal law policy of the Commonwealth and each of the States and Territories; and are significant compared to the penalties applied under other regulatory schemes.[117]

115 Submission No.77, pp.86-7 (IOGTR).

116 Submission No.77, p.87 (IOGTR).

117 Submission No.77, p.87 (IOGTR).

4.141 The Australian Law Reform Commission, while not directly commenting on the Bill, argued that there is a need for a range of regulatory and penalty mechanisms within a regulatory regime. The Commission argued that:

> A range of penalty options provides the flexibility to fit the penalty to the act or omission, escalating the penalty in relation to persistent or serious non-compliance. A pyramid [approach]…provides a range of penalty options, with the most serious appearing at the apex…an effective pyramid approach leads to cost-effective regulation…Cost effective regulation allows resources to be devoted to the most effective forms of regulatory activity with the most severe sanctions reserved for the few serious or persistent offenders…a regulatory regime should include an escalating range of penalty responses. An example…includes, from the base of the pyramid, persuasion, warning letter, civil penalty, criminal penalty, licence suspension, licence revocation.[118]

Adequacy of penalties

4.142 Several submissions argued that the penalties under the proposed legislation are inadequate. Submissions emphasised that in order for penalties to be effective in ensuring compliance, they need to be sufficiently large.[119] Submissions, however, generally welcomed the Government's decision to introduce strict liability offences to the Bill since the release of the consultation draft.[120]

4.143 ACF stated that penalties for committing an offence under the Bill (clauses 32 to 38) are 'grossly inadequate', particularly for strict liability offences and should be increased to provide a minimum penalty standard that 'is commensurate with the potentially irreversible and unlimited scale of the damage'.[121] Friends of the Earth (Fitzroy) argued that the maximum penalties for infringing the provisions of the Bill should be increased ten fold.[122]

4.144 Another submission argued that the penalties for a corporation in the case of a breach that causes significant damage – of up to $1.1 million – 'would seem out of proportion to a potential catastrophe' and a fine of this size 'is minuscule to the vast sums multinational corporations hope to profit by with this technology. It would seem a very small deterrent'.[123]

4.145 The Parliamentary Library noted that environmental statutes commonly impose, in addition to a monetary penalty, a further penalty for each day a breach

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118 Submission No.23, p.2 (ALRC).

119 Submission No.40, p.8 (ACF); Submission No.51, p.13 (Friends of the Earth (Fitzroy)); Submission No.34, pp.13-14 (ACEL); *Committee Hansard*, 24.8.00, pp.308-9 (ACF).

120 Submission No. 40. p.8 (ACF); Submission No.51, p.13 (Friend of the Earth (Fitzroy)).

121 Submission No.40, p.8 (ACF).

122 Submission No.51, p.13 (Friends of the Earth (Fitzroy)).

123 Submission No.17, p.3 (National Genetic Awareness Alliance).

continues, thus creating a strong incentive to remedy breaches as quickly as possible. The Library noted that this approach has not been adopted in the Bill.[124] For example, under the *Protection of the Environment Operations Act 1997* (NSW) the penalties for individuals who cause water and air pollution are $120 000 and $60 000 for each day the offence continues.[125]

4.146 Further, environmental statutes often provide for terms of imprisonment in addition to substantial fines. For example, the *Environment Protection and Biodiversity Conservation Act 1999* (Cth) prescribes jail terms of up to 2 years for offences relating to endangered or threatened species. The maximum fine payable for these offences is 1000 penalty points. Under the *Protection of the Environment Operations Act 1997* (NSW) the maximum penalty for wilfully or negligently causing harm to the environment by disposal of waste, leaks or spillage is $250 000 or 7 years imprisonment.[126] Whereas other, less serious, offences contained in the Gene Technology Bill (clauses 175, 187 and 192) may result in a term of imprisonment, no terms of imprisonment are available as an alternative penalty for major offences (clauses 32 to 38), even though they may result in substantial environmental damage or health hazards.[127]

Conclusion

4.147 The Committee believes that monetary penalties for breaches of a condition of licence are insufficient and need to be increased to act as a sufficient deterrent. In particular, the Committee considers that the penalties for strict liability offences (up to $22 000 for an individual and $110 000 for a corporation) are totally inadequate. The Committee also believes that in addition to a monetary penalty, a further penalty for each day a breach of a licence continues should apply to create an incentive to remedy breaches as quickly as possible. The Committee further considers that terms of imprisonment should be available as an alternative to a monetary penalty for major offences under the Bill.

Recommendations

The Committee RECOMMENDS that the Bill be amended to require that monetary penalties for breaches of a condition of a licence, especially in the case of a breach of condition of licence that causes significant damage or is likely to cause significant damage, be substantially increased.

The Committee RECOMMENDS that the Bill be amended to provide, in addition to a monetary penalty, a further penalty for each day a breach of a licence continues.

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124 Parliamentary Library, p.30.

125 Parliamentary Library, p.44. See also Submission No.82, p.5 (Environs Kimberley).

126 Parliamentary Library, pp.30, 44. See also Submission No.82, p.5 (Environs Kimberley).

127 Parliamentary Library, p.30.

The Committee RECOMMENDS that the Bill be amended to provide for terms of imprisonment to be imposed for major offences relating to breaches of condition of a licence.

Cost recovery and funding measures

4.148 Under the proposed regulatory system, it is intended that the costs incurred by the Regulator as a result of fulfilling his or her functions under the legislation will be 100 per cent cost recovered from the users of the regulatory regime. The Gene Technology Bill provides that the Regulator may charge for services provided by, or on behalf of, the Regulator in the performance of the Regulator's functions. The Gene Technology (Licence Charges) Bill 2000 provides an additional capacity for the Regulator to make charges in respect of licences.[128]

Opposition to full cost recovery

4.149 Most submissions and other evidence to the inquiry from a broad range of consumer, industry and environmental groups, opposed full cost recovery.[129]

4.150 The research and development sector expressed concern that cost recovery would further stretch already limited research budgets and inhibit 'blue skies' or innovative research. CSIRO commented that the organisation is by far the largest user of the existing GMAC system and is concerned that:

> …there has been inadequate policy discussions of the impact that full cost recovery may have on Australia's international competitiveness and capacity to continue its world-class basic research in this field. We are deeply concerned that full cost recovery may inadvertently increase the emphasis on commercial applications where regulatory costs can be passed on to commercial partners and diminish research aimed at increasing our understanding of molecular genetics, environmental impact and public good application of gene technology.[130]

4.151 CSIRO further stated that assuming an overall stable research budget, higher compliance costs through full cost recovery of regulatory oversight of basic research 'are likely to impact on the overall research and post-graduate education budget of universities and organisations such as CSIRO. They are also likely to flow onto

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128 Submission No.77, p.94 (IOGTR).

129 See, for example, Submission No.6, p.4 (Consumers' Association of SA); Submission No.17, p.3 (National Genetic Awareness Alliance); Submission No.36, p.3 (Valley Seeds Pty Ltd); Submission No.44, p.3 (Seed Industry of Australia); Submission No.58, pp.1-2 (Australian Biotechnology Association); Submission No.71, p.8 (AFGC); Submission No.61, p.5 (Aventis CropScience Australia Pty Ltd). See also *Committee Hansard*, 24.8.00, pp.335, 344-5,349-50 (Florigene Ltd); *Committee Hansard*, 25.8.00, pp.375, 379-80 (Avcare); *Committee Hansard*, 25.8.00, p.400 (AFGC); *Committee Hansard*, 25.8.00, pp.414, 417 (CSIRO).

130 CSIRO, Additional Information dated 20 September 2000.

reduced outputs, international scientific competitiveness and education of future scientists'.[131]

4.152 Australian industry utilising gene technology expressed concerns that, because it is an emerging industry with long lead times to commercialisation where the smaller companies are often making net losses, the introduction of fees and charges would retard the growth of the companies. Small biotechnology companies indicated that cost recovery would disadvantage fledging companies compared to multi-nationals. Valley Seeds Pty Ltd stated that the proposed arrangements:

> …will create a registration system that is too costly for small Australian companies to participate in this technology. We are a small company…any fees that are imposed, in addition to the higher compliance costs will put us and other Australian companies at a distinct disadvantage compared to larger multinationals.[132]

4.153 State Governments also indicated concerns with full cost recovery impacting on emerging biotechnology industries. The Western Australian Government stated that any cost recovery model must demonstrate:

> …its ability to ensure the development of Australian industry is not restricted by the application of full cost recovery principles that place an undue impost on a new industry.[133]

4.154 Avcare Ltd also commented that cost recovery arrangements needed to take into account the 'particular situation of smaller players…Cost recovery will hit them harder than the larger organisations'.[134]

4.155 Consumer groups and others expressed concern that full cost recovery may make the Regulator 'captive' of industry. The Consumer Food Network of the Consumers' Federation of Australia stated that 'we oppose 100% cost recovery from industry for the running costs of the GTR. This could lead to perceptions of "industry capture" of the regulator'.[135] AFGC also stated that:

> A key element of community confidence in the operation of the OGTR is independence, particularly from commercial interests. Retaining this independence, and perhaps more importantly the public perception of independence, while relying for funding on revenue generated from those being regulated will be problematic. Both the Regulator and industry will be open to criticism of collusion, with the Regulator particularly exposed as

131 Submission No.102, p.4 (CSIRO).

132 Submission No.36, pp.3-4 (Valley Seeds Pty Ltd).

133 Submission No.91, p.2 (Western Australian Government). See also Submission No.89, p.6 (Tasmanian Government).

134 Submission No.32, p.9 (Avcare Ltd).

135 Submission No.50, p.5 (Consumer Food Network).

being unduly influenced by industry through reliance on funding from granting permission to develop GMOs.[136]

4.156 Several submissions and other evidence emphasised the strong 'public interest' argument in ensuring the safety of all GMOs, and that it would be appropriate for Australian governments to pay all or at least part of the costs of the regulatory system. The Consumer Food Network stated that 'the GTR should be funded totally from consolidated revenue, as it will be performing a community service in protecting the health of people and the environment'.[137]

4.157 CSIRO also suggested that in determining the funding base for the Regulator 'account should be taken of the significant public benefits that may flow from enhanced knowledge of environmental impacts of GMOs, the assurance to the public about the safety of GMOs and specific, public benefit products that may arise from the research activity'.[138]

Alternative approaches

4.158 Several non-industry groups argued that OGTR should be taxpayer funded, especially to avoid any perception of 'industry capture' of the Regulator. The Consumer Food Network argued that the Regulator should be totally funded from consolidated revenue.[139] Some groups, such as the Organic Federation of Australia and the ACF GeneEthics Network, argued that if a form of cost recovery is introduced, the revenue from any licence fees should go directly into consolidated revenue.[140]

4.159 Evidence indicates that few regulatory regimes overseas impose full cost recovery. The KPMG Report into cost recovery stated that in overseas countries 'the spectrum for cost recovery for regulatory activities ranges from "recovery of the costs of selected activities" (e.g. release into the environment) in some European countries to zero cost recovery in the USA. Australia is relatively rare in pursuing full-cost recovery as a principal approach to regulatory charges'.[141] No country in the European Union charges fees that aim to recover the full cost of their regulatory regimes.[142] In

136 Submission No.71, p.10 (AFGC). See also Submission No.32, p.9 (Avcare Ltd).

137 Submission No.50, p.5 (Consumer Food Network).

138 Submission No.102, p.4 (CSIRO). See also Submission No.71, p.14 (AFGC); Submission No.58, p.2 (ABA); *Committee Hansard*, 28.8.00, p.400 (AFGC).

139 Submission No.50, p.5 (Consumer Food Network). See also Submission No.85, p.12 (ACF GeneEthics Network); Submission No.54, p.20. (Organic Federation of Australia).

140 Submission No.54, p.20 (Organic Federation of Australia); Submission No.85, p.12 (ACF GeneEthics Network).

141 KPMG Consulting, *A model for cost-recovery in the Office of the Gene Technology Regulator*, September 2000, p.30.

142 KPMG Report p.41.

the case of Canada, the fee schedules only cover a small range of processes, such as for confined trials or intentional release trials, and do not fully recover costs.[143]

4.160 The IOGTR stated that of the five regulatory agencies that interface with the proposed regulatory system for GMOs in Australia, all have some capacity to recover costs associated with the regulatory systems from the users of those systems. The majority of these agencies phased in cost recovery over a number of years. The Therapeutic Goods Administration introduced a policy of 50 per cent cost recovery in 1991, which by 1998-99 had increased to 100 per cent. Under its cost recovery policy all costs, including policy advice and compliance activities, are recovered from the TGAs client base. The TGA is, however, different from the regulatory regime proposed under the Gene Technology Bill in that it does not issue licences.[144]

4.161 The other regulatory agencies – the National Registration Authority, the Australian Quarantine and Inspection Service and the National Industrial Chemicals Notification and Assessment Scheme – are 100 per cent cost recovered for operational activities, but do not recover costs for policy advice. The Australia New Zealand Food Authority has not implemented cost recovery, but has the capacity to charge for applications which are outside the scope of its work program.[145]

4.162 Industry and primary producer groups argued that the costs of the proposed regulatory system should be split between 'public good' functions, which would be paid for by the community generally, and the cost of processing applications to be paid for by industry. Avcare Ltd argued that the costs of operation of the Regulator should be apportioned between 'public benefit' functions and services for which a fee to users would be charged.[146] The National Farmers' Federation (NFF) also supported the inclusion of a charge for assessing applications only.[147] Avcare also argued that in determining 'fees for services', charges to industry and scientific agencies should be phased in over a 5 year period.[148] A phase-in period was also supported by the NSW Farmers' Association. The Association argued that 'for a handful of applications to bear the full costs of the system in the early years would be unrealistic'.[149]

4.163 Florigene Ltd and Nugrain Pty Ltd argued that if fees are to be applied, all applicants should be treated equally – applicants from industry should not subsidise university or government research projects. The fees should also be 'very low' – if

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143 KPMG Report, p.35. See also Submission No.42, p.8 (Florigene Ltd & Nugrain Pty Ltd). See also *Committee Hansard*, 24.8.00, p.335 (Florigene Ltd).

144 Submission No.77, p.92 (IOGTR).

145 Submission No.77, pp.92-3 (IOGTR).

146 Submission No.32, p.9 (Avcare Ltd). See also Submission No.71, p.14 (AFGC); Submission No.59, p.4 (MLA).

147 Submission No.88, p.3 (NFF). See also Submission No.76, p.5 (NSW farmers' Association) .

148 Submission No.32, p.9 (Avcare Ltd). See also Submission No.42, p.8 (Florigene Ltd & Nugrain Pty Ltd).

149 Submission No.76, p.5 (NSW Farmers' Association).

they are high, expenditure of research grant money will be skewed towards small scale and field trial evaluation, instead of research. Fees should also be set on the basis of the time actually spent by the Regulator on each application and not a flat fee. If this is not done, the smaller crops – crops where there are is no environmental impact or products already cleared by GMAC may be unable to be commercialised.[150]

4.164 State Governments emphasised a need for a partial and phased approach to cost recovery indicating that the question of cost recovery is still subject to negotiations with the Commonwealth. The Western Australian Government stated that:

> …further detail must be provided on the cost recovery model, and its ability to ensure the development of Australian industry is not restricted by the application of full cost recovery principles that place an undue impost on a new industry. The overall costs associated with the proposed national regulatory system, and the extent to which those costs should be recovered from GMO proponents, remains the subject of negotiations.[151]

4.165 The Tasmanian Government stated that:

> It is imperative to note that there is generally not a level playing field in respect of the financial abilities of large and small biotechnology firms. While cost recovery is appropriate where researchers are "tied" to large biotechnology firms, in cases where public policy considerations dictate it may be appropriate for Government to bear at least part of the costs. This could initially be on a partial or "phasing in" basis as has occurred in other regulatory agencies.[152]

4.166 Evidence to the Committee also argued that any costing model needs to make a distinction between the impact of full cost recovery on research as opposed to the impact on industry. The National Health and Medical Research Council (NHMRC) argued that for many commercial applications there is a clear product which has the potential to provide an income stream to the proponent and thus may warrant some form of cost recovery. The Council noted, however, that much health and medical research is conducted at the fundamental end of the research spectrum:

> There is often no immediate benefits flowing to the institution or the proponent from the conduct of such research, unlike the case with the conduct of a field trial, prior to commercial release, of a genetically engineered crop for example. The cost of such a regime, and any charges imposed by the GTR, will thus be internalised by those who conduct health and medical research. Moreover, in the vast majority of cases, the benefits

150 Submission No.42, p.8 (Florigene Ltd & Nugrain Pty Ltd).

151 Submission No.91, p.2 (Western Australian Government). See also *Committee Hansard*, 14.8.00, p.28 (Western Australian Government).

152 Submission No.89, p.6 (Tasmanian Government).

> flowing from health and medical research are a public good…but little opportunity for the proponent to directly recoup these internalised costs.[153]

KPMG report on cost-recovery options

4.167 In May 2000, the IOGTR engaged an independent consultant KPMG Consulting to fully cost the regulatory regime and provide options for recovering the costs of the activities and functions of the OGTR.[154]

4.168 The KPMG Report concluded that a full cost recovery regime 'is considered to be impracticable in (at least) the first three to five years of operation of the OGTR'.[155] The Report stated that:

> …there is a degree of fragility in attempting to fully recover all the costs of the OGTR – especially in the first few years of operation of the Office. That is not to say that such a regime could not be introduced at a later stage when the gene technology industry has evolved to achieve a sustainable market position in Australia. It merely emphasises the fact that, currently, there is limited industry income to fund any fees and charges with any degree of equity.[156]

4.169 The Report estimated that the total costs of operating the GTR/OGTR would be $7 787 786 in the first year.[157]

4.170 The Report stated that the Government's policy of requiring full cost recovery needs to recognise that most clients of the GTR – approximately 94 per cent of all applications for gene technology dealings – are publicly funded organisations undertaking research, with little or no budgetary capacity to address additional cost imposts without detracting from the funds available for gene technology research.[158] KPMG argued that:

> Consequently, an inappropriate cost recovery regime could lead to much proposed R&D work not being undertaken in Australia, or being moved off-shore. Under either scenario, Australia would be a major loser – both economically and in its attempt to remain in the global mainstream of gene technology development.[159]

4.171 In addition, the Report argued that most companies dealing in gene technology will have limited commercial production for, at least, the next few years –

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153 Submission No.103, pp.9-10 (NHMRC).

154 Submission No.77, pp.97-103 (IOGTR).

155 KPMG Report p.ii.

156 KPMG Report, p.iii.

157 KPMG Report, p.iii.

158 KPMG Report, p.i.

159 KPMG Report, pi.

'as a consequence, it is unlikely that many such companies will have a sustainable income stream to support any significant level of fees–which can be passed on to the end consumer of any products they market. This issue will be an important factor in the sustainability and development of the gene technology industry'.[160]

4.172 KPMG presented four cost recovery options. The latter three include a levy across the different sectors of the gene technology industry:[161]

- *Option 1* (full cost recovery) – direct fees for applications of $4.9 million (63 per cent) and $2.9 million (37 per cent) for monitoring;
- *Option 2* (75 per cent cost recovery) – direct fees for applications of $2.8 million (36 per cent) and $1.6 million (21 per cent) for monitoring; levy of $1.4 million (18 per cent); and Government Assistance $1.9 million (25 per cent). This and subsequent options cover the full cost of the OGTR by a combination of reduced application fees, an industry levy and a proportional level of Government Assistance.
- *Option 3* (50 per cent cost recovery) – direct fees for applications of $1.6 million (21 per cent) and $0.9 million (11 per cent) for monitoring; levy of $1.4 million (18 per cent); and Government Assistance $3.9 million (50 per cent);
- *Option 4* (25 per cent cost recovery) – direct fees for applications of $0.3 million (4 per cent) and $0.2 million (3 per cent) for monitoring; levy of $1.4 million (18 per cent); and Government Assistance $5.9 million (75 per cent).[162]

4.173 The Report stated that 'best practice' across a range of cost recovery regimes indicates that:

- those imposing costs on the regulator should pay the charges necessary to cover those costs;
- Government should provide funding where there are public interest, public good or equity reasons;
- costs charged to applicants should relate only to the costs of processing, assessing and deciding on applications;
- charges should be imposed for services that provide identifiable recipients with direct benefits beyond those received by the general public;
- where there are both public and private benefits from a service, fees should be less than the full cost of delivering the services;

160 KPMG Report, p.i.

161 The levy has three rates: research/universities – $4000; small companies – $20 000; large companies – $200 000.

162 KPMG Report, p.iii; Part 2, p.15.

- where direct beneficiaries of the regulatory process can be identified, they, rather than the taxpayers in general, should pay for the services creating the relevant benefits; and
- the Government should not seek to make a profit from regulatory charges.[163]

Conclusion

4.174 Evidence to the inquiry argued strongly against the introduction of full cost recovery for the proposed regulatory scheme. The Committee, while not supporting full cost recovery, supports a system of partial cost recovery. The Committee believes that the introduction of full cost recovery would compromise the integrity of the Office of the Regulator, noting that a body charged with protecting human health and environmental safety would be seriously compromised if it were funded entirely by the groups it is supposed to be regulating.

4.175 The Committee is also concerned about the effect full cost recovery would have on the future of research and development in the emerging biotechnology area. Evidence to the Committee, including the KPMG Report, emphasised that full cost recovery would lead to proposed research and development work not being undertaken in Australia or being moved off-shore. The Committee believes that it is essential that the development of Australian industry is not restricted by the application of full cost recovery principles that place an undue impost on a new industry.

4.176 While the Committee believes that a partial system of cost recovery should be introduced with industry and other users contributing in addition to part funding by Government, the Committee notes that the Productivity Commission is currently considering the specific issue of cost recovery as it applies to Government instrumentalities. The Committee therefore believes that further discussion about, and proposals (including the KPMG Report) relating to, cost recovery and the operation of the OGTR be deferred until after the Productivity Commission report and its recommendations are available and that, until such time, the Government fully fund the operation of the OGTR.

4.177 The Committee notes that evidence received during the inquiry indicated support for a cost recovery system that imposed differential fees and charges in respect of universities and research organisations; smaller-scale companies in the start-up research and development phase; and larger, more established companies so that innovative research and smaller biotechnology companies are not disadvantaged under the cost recovery regime. The Committee also notes that evidence received indicated that there were strong ‘public interest’ arguments relating to the public benefits that will flow from the development of gene technology that support a Government contribution towards the cost of the regulatory regime.

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163 KPMG Report, p.ii.

Recommendations

The Committee RECOMMENDS that further discussion about, and proposals (including the KPMG Report) relating to, cost recovery and the operation of the OGTR be deferred until after the Productivity Commission report and its recommendations are available. The Committee further RECOMMENDS that until such time, the Government fully fund the operation of the OGTR.